

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/766,403	Applicant(s) BELARDINELLI ET AL.
Examiner LAWRENCE E. CRANE	Art Unit 1623

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 02 October 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
b) ☐ They raise the issue of new matter (see NOTE below);
c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 74, 77 and 79-89.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. ☒ Other: See attached Interview Summary.

/Lawrence E. Crane/
Primary Examiner, Art Unit 1623

Continuation of 11, does NOT place the application in condition for allowance because:

examiner respectfully disagrees with appellant's argument that the inventions encompassed by the patent claims in each of the obviousness-type double patenting rejections of record are materially different from the invention encompassed by the instant claims. The distinction appellant argues is that the term "excipient" must be construed strictly according to the definition of said term specified in the disclosure of the particular patent. Examiner respectfully disagrees because to adopt this strict an interpretation of the scope of patentable subject matter would in effect eliminate variations reasonably within the scope of patented subject matter that are available to the ordinary practitioner as a consequence of routine experimentation directed to the optimization of claimed subject matter. In addition appellant has equated the subject matter uncovered as a result of routine optimization (and claimed herein) with subject matter obtained by hindsight reconstruction, a view that examiner finds to be at odds with examiner's understanding of the actual scope of subject matter encompassed by a patent claim, a scope that is generally not understood to be strictly limited by disclosure definitions as a consequence of the "corona" of obvious variations generally known to be bordering patented subject matter. And finally examiner does not agree with appellant's assertion because the separate patentability of the particular compositions claimed herein and methods of coronary vessel visualization related thereto, are not supported by any disclosure of unexpected results. Examiner notes that method of treatment claims citing the compound CVT-3146 as an agent capable of inducing short term coronary blood vessel relaxation to facilitate X-ray visualization of vessel physical condition following administration of an appropriate contrast agent are identical to the method claims disclosed for this compound in the issued patents except for the particular pH range and the particular identities of the carriers present in the pharmaceutical compositions. The selection of any particular pH range or any particular set of pharmaceutically acceptable carriers or excipients is found to be well within the scope of routine experimentation as provided for by the disclosures in the relevant portions Chapters 40 and 66 of the 16th edition of Remington's Pharmaceutical Sciences cited as secondary references in each rejection.

Therefore, examiner affirms the previous findings that the instant claims are not patentably distinguishable from the patented claims cited in the obviousness-type double patenting rejections of record.